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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters Products Liability Litigation	NO. MD-15-02641-PHX-DGC **DEFENDANTS' RESPONSE TO PLAINTIFFS' BRIEF ON FOREIGN REGULATORY MATERIALS**

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard")submit this, their Response to the Plaintiffs' Brief on Foreign Regulatory Materials (the "Plaintiffs' Brief"), as follows:

I. Bard's International Entities Had Neither the Autonomy Nor the Responsibilities that Plaintiffs Claim, With the Result that the Discovery the Plaintiffs Seek is Irrelevant in This Litigation

The discovery sought by the plaintiffs regarding Bard's foreign sales entities is irrelevant to this litigation and should not be permitted. There does not appear to be a single international plaintiff among the hundreds of individuals who have filed lawsuits in

this MDL proceeding. More importantly, Bard's foreign sales entities do not, as the plaintiffs claim, have substantial autonomy and responsibility with regard to the marketing of and regulatory activity regarding[1] IVC filters. As the testimonial and documentary evidence demonstrates, Bard's Tempe, Arizona facility (from which the plaintiffs are already obtaining voluminous discovery) handles all substantive activities regarding IVC filters. The plaintiffs therefore should not be permitted to require an extremely burdensome fishing expedition to collect materials having little or no relevance to this litigation.

First, Bard addressed the plaintiffs' contention regarding Bard's foreign sales entities in their responses to the plaintiffs' interrogatories, served on February 26, 2016. Bard later reiterated that Bard's foreign sales entities serve "the limited function of international distribution and the filing of foreign regulatory submissions" via correspondence dated March 4, 2016. Exhibit A.

Rob Carr's testimony is consistent with the representations made in Bard's responses to the plaintiffs' interrogatories and establishes that Bard's foreign sales entities had very little autonomy or responsibility in foreign regulatory or marketing activity, but were merely "commercial sales structures in those regions and/or countries" that essentially acted as liaisons between BPV and the foreign regulatory authority. Ex. B, Carr Dep. Tr., March 18, 2016, 42:8-18, 45:22-46:7. For instance, when asked what the "flow of command" would be for filing "the equivalent to a 510(k)" internationally, Mr. Carr testified that [BPV] handles the regulatory burden, "supply[ing] the required documentation, in that case to the Australian entity, who laisons [sic] with the Australian regulatory branch." *Id.*, 19:22-20:4. Mr. Carr also testified that, when products are developed, BPV determines the applicable regulatory testing burden and regulatory standards in each country in which Bard intends to launch a product, and, at the end of the

[1] Nor are the foreign entities repositories of separate complaint files. All of the complaint files, both internationally and domestically, are prepared in Tempe. All of those complaints, including the foreign complaints, are contained in the Trackwise database. All complaints in that database have been provided to the plaintiffs.

development project, puts together the supporting regulatory documentation to allow Bard to file for regulatory approval in that country. *Id.* at 99:14-100:18. Finally, Mr. Carr explained that foreign "marketing materials are developed and provided by BPV, by the filter team in this case," and that foreign entities "don't in any way develop content or supportive documentation for any marketing collateral they would use." *Id.* at 55:24-57:16.

The plaintiffs' selective quotation, and characterization, of Mr. Carr's testimony creates a facile appearance of autonomy and responsibility for Bard's foreign entities, but a closer look at Mr. Carr's testimony reveals the inaccuracy of that characterization. For instance, immediately after the portion of Mr. Carr's testimony selectively emphasized in the Plaintiffs' Brief regarding Bard's foreign entities ability to make simple changes to IFUs (such as providing the appropriate indication for use, and approving such changes locally), Mr. Carr reiterated that not every country even has its own regulatory team, and that even when they do, it is merely "a regulatory group within their commercial structure that, again, liaises with the [foreign] government and BPV. We supply all the pertinent information, answer all questions. They provide the documentation and translations back and forth." *Id.* at 57:17-59:4. In sum, Mr. Carr's testimony establishes not that Bard's foreign sales entities acted autonomously, as the plaintiffs claim, but that Bard's foreign sales entities were merely sales structures that, at times, liaised with foreign regulatory entities on BPV's behalf, using information and materials developed in Tempe.

The documentary evidence similarly confirms that Bard's foreign entities had very little autonomy and responsibility in the marketing or regulatory spheres. On the marketing side, internal marketing document control forms produced in this litigation demonstrate that it is BPV developing and approving international materials, not the international entities.[2] In these documents, even where the international entities are providing commentary on these materials, it is to change a facsimile number or perform a

[2] *E.g.*, Ex. C, BPV-17-01-00242282.

minor wording change.[3] Moreover, although Mr. Carr acknowledged that Bard's foreign entities were allowed to translate documents and IFUs, BPV provided its foreign entities with IFUs for its products already translated into eighteen (18) languages.[4]

Even the exhibits attached to the Plaintiffs' Brief reinforce Bard's foreign sales entities' limited role as liaisons. For example, in the plaintiffs' Exhibit 4, although David Marshall, Director of Regulatory Affairs & Quality Assurance for Bard Europe, references consultations he had with an individual at the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA"), the impetus of such consultations was changes to an IFU made and disseminated by BPV. Further, a careful reading of the exhibit also reveals that the scope of Mr. Marshall's consultations was to advise the United Kingdom's foreign regulatory agency of the IFU changes on BPV's behalf and inquire whether additional action by BPV was necessary. With MHRA satisfied with the changes, Mr. Marshall informed BPV that it need take no further action. This interaction fits squarely within Bard's foreign sales entities' role as liaison between BPV and foreign regulatory authorities.

Another Bard document used by the plaintiffs at depositions exemplifies Bard foreign sales entities' limited role as liaisons between BPV and foreign regulatory authorities.[5] In that document, Bard's international entity receives questions from MHRA, and Bard's foreign entity passes along the request, asking BPV to provide a response that the international entity, in turn, can provide the MHRA. John Van Vleet at BPV then assembles a team at BPV to craft a response, and the team crafts a response and provides relevant documentation for dissemination to the MHRA. Further confirming the international Bard entity's limited role, the document also mentions previous international issues that BPV had "handled in person." This document aptly demonstrates Bard's

[3] *E.g.*, Ex. D, BPV-17-01-00242221.
[4] *E.g.*, Ex. E, Denali OUS IFU, BPVEFILTER-01-00542477.
[5] Ex. F, BPVEFILTER-01-00041005. The plaintiffs marked this document as an exhibit during the August 9, 2016 deposition of BPV employee Maureen Uebelacker.

foreign sales entities' limited role as liaisons between BPV and foreign regulatory entities, and the fact that the Tempe facility is providing all substantive content.

Accordingly, as Bard has maintained throughout this litigation, and demonstrated through the evidence presented by both parties, Bard's foreign sales entities have limited autonomy and responsibility. As such, the extensive discovery the plaintiffs seek regarding Bard's foreign entities is irrelevant to the claims at issue in this litigation and should not be permitted. *See Steel Erectors, Inc. v. AIM Steel Int'l, Inc.*, 312 F.R.D. 673, 676–77 (S.D. Ga. 2016).

II. Even if Relevant, the Discovery the Plaintiffs Seek Would be Burdensome and Expensive, and is Not Proportional to the Needs of this Case

Even if the plaintiffs' requested discovery had some relevance to the issues in this litigation—which Bard denies—that significance is marginal at best, and the burden of the proposed discovery greatly outweighs any marginal benefit it could possibly provide. Therefore, the plaintiffs' requested discovery regarding Bard's foreign sales entities is not proportional to the case and should not be permitted. *Elkharwily v. Franciscan Health Sys.*, No. 3:15-CV-05579-RJB, 2016 WL 4061575, at *2 (W.D. Wash. July 29, 2016); *Mylan Pharmaecuticals v. Celgene Corporation*, 2016 WL 2943813 (D. N.J. May 20, 2016); *Moore v. Lowe's Home Centers, LLC*, No. 14-1459 RJB, 2016 WL 687111, at *5 (W.D. Wash. Feb. 19, 2016) (ESI regarding individuals not involved in the claims made by the plaintiffs not permitted as not proportional to the case).

As discussed at the recent case management conference, none of the claims made by the plaintiffs in this case involve injuries or actions in foreign countries. The fact that Bard's foreign sales entities simply acted as liaisons between BPV and foreign regulatory entities, as discussed above, further establishes the immateriality of the plaintiffs' requested discovery to the issues in this case.

Moreover, the substantial cost of obtaining and processing the required documents would greatly outweigh any marginal benefit arguably associated with such discovery. The plaintiffs' requested discovery regarding international entities is far from the simple

undertaking they posit. Such an undertaking would be incredibly burdensome and costly to Bard, and would be difficult, if not impossible, to complete before the close of fact discovery. As discussed during the Court's recent hearing, Bard has had numerous foreign sales entities spanning the globe for the last 13 years,[6] and the plaintiffs seek discovery of all correspondence from all custodians at those entities regarding all contacts with all foreign regulatory authorities involving all Bard filters sold abroad since 2003. To comply with this request, Bard would have to identify the applicable custodians from all of its foreign sales entities for the last 13 years; collect ESI from those custodians, and then search and identify all foreign regulatory correspondence from those custodians during that timeframe. In addition, Bard would then have to review the ESI for relevance and privilege. Finally, Bard would have to ensure that the production complies with the various data and privacy laws of the countries in which the foreign entities are located,[7] redact the documents pursuant to applicable law, and then produce the redacted documents.

For the reasons stated above, not only is the plaintiffs' requested discovery of no importance to the issues in this case, the burden of obtaining and producing such discovery would far exceed any marginal benefit it could provide in this litigation. Thus, the plaintiffs' requested discovery simply is not proportional to the needs of this wholly domestic case, and should not be permitted.

DATED this 6th day of September, 2016.

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[6] By way of example, among other countries, Bard has entities in Canada, Korea, Australia, India, Singapore, Malaysia, Italy, Ireland, the United Kingdom, Denmark, the Netherlands, Sweden, Norway, Finland, Mexico, Chile, Brazil, and China.

[7] For instance, the EU Data Protection Directive, 95/46/EC, may apply to data and documents collected from Bard's sales entities located in the European Union.

~and~

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of September, 2016, I electronically filed Defendants' Response to the Plaintiffs' Brief on Foreign Regulatory Materials with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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